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09/752,939	12/29/2000	Bruce L. Gibbins	KCX-1743 (64665657US02)	9231
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/752,939	<b>Applicant(s)</b> GIBBINS ET AL.	
	<b>Examiner</b> Isis Ghali	<b>Art Unit</b> 1611	<b>AIA (First Inventor to File) Status</b> No

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2012.  
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) See Continuation Sheet is/are pending in the application.  
 5a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1,2,4,6,21,23-28,31-34,38-41,43,45-54,56,57,59,61-70 and 72 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

#### Certified copies:

- a) ☐ All    b) ☐ Some    c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Interim copies:

- a) ☐ All    b) ☐ Some    c) ☐ None of the: Interim copies of the priority documents have been received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 3) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 4) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1, 2, 4, 6, 21, 23-28, 31-34, 38-41, 43, 45-54, 56, 57, 59, 61-70, 72.

### **DETAILED ACTION**

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 01/18/2012.

Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-72 previously presented.

Claims 8, 35, 42, 55, 58 and 71 are canceled by the amendment filed 01/18/2012.

Claims 1, 2, 4, 6, 21, 23-28, 31-34, 38-41, 43, 45-54, 56, 57, 59, 61-70, 72 are pending and included in the prosecution.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/18/2012 has been entered.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of 35 U.S.C. 112(a):  
(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 2, 4, 6, 21, 23-28, 31-34, 38-41, 43, 45-54, 56, 57, 59, 61-70, 72 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 1, 38 and 39 recite “carbonate salts” as catalyst to produce oxygen. This is new matter not supported by the original disclosure. Recourse to the specification, applicants used carbonate salts to produce carbon dioxide and not oxygen. Paragraph 0164 of the published application disclosed:

“If the decomposition of hydrogen peroxide was too strong, polyacrylamide was degraded. This can be avoided by lowering the amount of hydrogen peroxide used or using an alternative decomposition catalyst, such as sodium carbonate. **Sodium carbonate as a catalyst formed suitable foam, and decomposed into carbon dioxide gas,** which is an acceptable residual.”

If applicant contends there is support for this limitation, then applicant is requested to specify the page and line of said support. In accordance to MPEP 714.02,

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applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Further, claims 21, 43 and 59, and claims 23-27, 45-49, and 61-65 that depend on claims 21, 43 and 59, lack written description. The claims recite many categories of active agents that encompass myriad of compounds. The claims recite ,among others, mycoplasma treatments, pharmaceuticals, chemotherapeutic agents, herbicides, growth inhibitors, indicators of change in the environment, enzymes, nutrients, vitamins, minerals, carbohydrates, fats, fatty acids, nucleic acids, nucleosides, nucleotides, amino acids, sera, antibodies and fragments thereof, lectins, immune, stimulants, immune suppressors, neurochemicals, cellular receptors, antigens, adjuvants, and radioactive materials. Applicants failed to describe reasonable number of members of the above categories that are suitable for inclusion in wound dressings. The specification gives no guidance to one of ordinary skill in the art regarding the claimed elements that are very broad. Claiming such categories of elements without partial or complete description of reasonable number of representatives of each category does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter and does not meet the written description requirement. For examples, the terms "pharmaceuticals", "fats", "neurochemicals", "herbicides", "enzymes", "chemotherapeutic agents", etc., are very broad and encompass myriad of compounds, known and unknown that may not be useful and even may be harmful for the wound, yet all can be used in the claimed device for treating wounds. What are herbicides that can be included in wound dressing? Herbicides are known to be toxic agents. What are

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mycoplasma treatments that can be included in wound dressing? What are sera and immune that can be included in wound dressing? Why "growth inhibitors" are included in wound dressing where tissue growth is needed as evidenced by the same claims that recite wound healing agents and growth promoters? The claimed elements are not known to be useful in wound dressing and applicants did not disclose their inclusion in wound dressings.

Claims employing limitation at the point of novelty, such as applicants', neither provide those elements required to practice the invention, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. Applicants were not in possession at the filing date of the present application of all claimed categories of active agents. The claimed terms and expressions encompass myriad of elements and applicants' claimed terms and expressions represent only an invitation to experiment regarding possible elements. Applicants failed to provide written description for the entire scope of the claimed terms and expressions in the instant specification. As such, it is not apparent that Applicants were actually in possession of, and intended to use, within the context of the present invention, the entire scope of the claims at the time the present invention was made.

Regarding the requirement for adequate written description of chemical entities, Applicants' attention is directed to MPEP § 2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F. 3d 1559, 1568 (Fed. Cir. 1997), cert denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties,

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"not a mere wish list or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F. 3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216,225 (W.D.N.Y. 2003).

With the exception of the specifically disclosed and known active agents for treating wounds, the skilled artisan cannot envision the detailed elements encompassed with the claimed categories of active agents. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiefs v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

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A genus, such as claimed expressions, can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, courts have indicated what does not constitute same. See, e.g., *In re Gostelli*, 10 USPQ 2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two compounds within a subgenus did not adequately describe such subgenus.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 4, 6, 21, 23-28, 31-34, 38-41, 43, 45-54, 56, 57, 59, 61-70, 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladin (US 5,792,090, of record) in view of Geistlich (WO 90/03810, IDS filed 08/10/2011), Murdock (US 2002/0042587, of record) and further in view of any of the article by Aubry "Chemical Source of Singlet Oxygen Peroxidation of Water-Soluble Singlet Oxygen Carriers with the Hydrogen Peroxide-Molybdate", currently provided, or Hoshino et al. (US 4,613,628, currently listed on PTO 892).

#### **Applicant's claims**

Claim 1 is directed to an oxygen-delivery wound treatment, comprising a biocompatible, single unit matrix for delivering oxygen, comprising

a) a swellable, cross-linked polyacrylamide polymer network,

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b) deliverable oxygen in elastic closed cells that are permeable to gas within the cross-linked polyacrylamide polymer network wherein after the polyacrylamide polymer network is cross-linked, the closed cell are formed by oxygen produced by reacting the catalyst and a second reactant, wherein the catalyst is a carbonate salt and wherein with use of the matrix, oxygen is delivered from the closed cells.

Claim 38 is directed to an oxygen delivery wound treatment device, comprising a biocompatible, single unit matrix for delivering oxygen, comprising;

a) a swellable, cross-linked polyacrylamide polymer network,

b) deliverable oxygen in elastic closed cells that are permeable to gas and within the cross-linked polyacrylamide polymer network a second reactant and a catalyst reaction occurred, wherein the catalyst is a carbonate salt, and

c) at least one active agent.

Claim 39 is directed to a biocompatible, single unit cross-linked polyacrylamide matrix, comprising a swellable, cross-linked polyacrylamide polymer network, and deliverable oxygen in elastic closed cells that are permeable to gas and within the cross-linked polyacrylamide polymer network at sites where a reaction of a catalyst and a second reactant ,occurred wherein the catalyst is a carbonate salt.

The present claims 1, 38 and 39 recite a product comprises matrix of closed cell foam of cross-linked polyacrylamide polymer containing oxygen produced by reaction of catalyst and reactant. The limitation of oxygen delivery is directed to intended use that imparts no patentability to composition claims. The limitation when oxygen is produced in the crosslinked polyacrylamide network is directed to process of making the product.

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Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985).

**Determining the scope and contents of the prior art (MPEP § 2141.01)**

Laden teaches wound dressing that supply oxygen to the wound for optimal healing and minimization of infection because the wound causes diffusion limited access and limits the oxygen supply to the wound (abstract; col.2, lines 28-31). The dressing comprises polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide or enzymes (col.6, lines 6-26). The catalyst is contained in the foam which absorbs hydrogen peroxide into the foam to produce oxygen (col.7, lines 48-55). The foam comprises guar gum or polyacrylamide, and further comprises collagen, i.e. non-gellable foam (col.4, lines 39-42; col.12, line 7). Laden teaches that the decomposition catalyst may be contained within a foam that can be open-celled foam or other foams disclosed by U.S. Pat. Nos. 4,193,813 or 4,703,108 (col.7, lines 47-57). These patents do not teach open-celled foam, i.e. teach closed cell foam.

**Ascertaining the differences between the prior art and the claims at issue,  
and resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)**

Although Ladin teaches polyacrylamide foam of any kind, however, the reference does not explicitly teach crosslinked polyacrylamide or closed cell foam in particular, or the catalyst is carbonate salts as instantly claimed by claims 1, 38 and 39.

Geistlich teaches wound healing composition in its preferred form comprises cross-linked polyacrylamide and gellable substance. The composition used in the form of dressing for direct application to the wound for delayed release of wound healing agents. The dressing has the advantage of very good compatibility with the wound and ease of removal from the wound without damage to the growing tissue. (See abstract; page 3, last paragraph; page 4). The dressing comprising growth factor (claim 1).

Murdock teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors (abstract; paragraphs 0035, 0049, 0050). The foam reservoir is closed cell foam wherein the closed cells can be produced chemically and contains gasses including oxygen (paragraph 0036). The closed cell foam provides thin matrix with high surface area with respect to the matrix (paragraphs 0011, 0016).

Aubry teaches that carbonate salt can be used to react with peroxide to release oxygen (see the entire document)

Hoshino teaches that reaction between peroxide and carbonate salt can be used to produce gas filled closed cell foam (see entire document, and column 5 and 8 in particular).

**Resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)**

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention provide wound dressing comprising polyacrylamide foam matrix containing oxygen produced by chemical reaction between peroxide and catalyst as taught by Ladin, and replace polyacrylamide by crosslinked polyacrylamide taught by Geistlich. One would have been motivated to do so because Geistlich teaches that cross-linked polyacrylamide wound dressing has the advantage of very good compatibility with the wound and ease of removal from the wound without damage to the growing tissue. One would reasonably expect formulating cross-linked polyacrylamide foam matrix containing oxygen that is produced chemically by the reaction of peroxide and catalyst wherein dressing is compatible with the wound and easily removed without damaging the underneath growing tissue.

Further, it would have been obvious to one having ordinary skill in the art at the art at the time of the invention to use the closed cell foam taught by Murdock in the foam matrix taught by the combination of Ladin and Geistlich because Murdock teaches that closed cell crosslinked polymer foam matrix is thin and has high surface area with respect to the matrix and oxygen can be delivered chemically in foam. One would reasonably expect formulating cross-linked polyacrylamide closed cell foam matrix containing oxygen that is produced by the reaction of peroxide and catalyst wherein the matrix is thin, yet can deliver therapeutic agents.

Using carbonate salt as catalyst for peroxide was known at the time of the invention as taught by any of Aubry or Hoshino, and one having ordinary skill in the art would have used carbonate salt based on the kind of gas to be produced.

Regarding the dependent claims, the active agents and additional elements claimed by the dependent claims are all taught by the cited references. Gellable materials taught by both Ladin and Geistlich and active agents taught by both Geistlich and Murdock. Applicants failed to show unexpected results obtained from the claimed active agents and additional elements in the dressing.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a) because the invention as a whole is taught by the combined teaching of the cited references.

### ***Response to Arguments***

8. Applicant's arguments filed 01/18/2012 have been fully considered but they are not persuasive.

Applicants argue that Ladin does not discuss the use of a carbonate salt as a catalyst used to decompose hydrogen peroxide into oxygen for use in an oxygen delivery device, which is a limitation of amended claims 1, 38, and 39. The examples in the pending application show that sodium carbonate is suitable as a decomposition catalyst because its use does not cause decomposition of the polyacrylamide matrix, which can be seen when ferric chloride and cupric chloride are used. Although Ladin briefly describes the use of water soluble catalysts, applicants argue that one of ordinary skill in the art would have been discouraged from using a carbonate salt as the particular water soluble catalyst based on the teaching of ferric chloride. Applicants note that not all "water soluble catalysts" have the same effect on the polyacrylamide matrix of the pending claims. One considering Ladin would not expend the additional time, effort, or resources in testing all water soluble catalysts to determine whether a catalyst such as sodium carbonate existed that would not cause the polyacrylamide matrix to dissolve as do the soluble catalysts disclosed in Ladin.

In response to this argument, it is argued that applicants used sodium carbonate as a catalyst to produce carbon dioxide gas and not oxygen, see paragraph 0164 of the present specification. The present claims require oxygen. Applicants admit that Ladin teaches water soluble catalysts, and the currently recited references, Aubry and Hoshino, show that carbonate was known at the time of the invention as a catalyst for peroxides. One having ordinary skill in the art would have used carbonate salt based on its suitability to react with peroxide to produce gas. One having ordinary skill in the art will not be discouraged from using carbonate salts by reading Ladin, rather, one having

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ordinary skill in the art would recognize that any water soluble catalyst is suitable based on the desired gas to be produced. Using carbonate taught by Aubry and Hoshino would have been obvious to one having ordinary skill in the art in absence of showing unexpected results in the present specification regarding producing oxygen using carbonate. It would have been simple substitution.

In KSR, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art," USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. "*In United States v. Adams*,... [t]he Court recognized that **when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.**" USPQ2d at 1395.

Court further stated that:

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. USPQ2d at 1396."

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Applicants argue that Geistlich and Murdock are only cited for teaching a cross-linked polyacrylamide and a closed cell foam for delivering active agents to a wound and do not cure the deficiencies of Ladin with respect to how oxygen is formed in the device via hydrogen peroxide and a carbonate salt catalyst. Therefore, the pending claims are not obvious when combining Ladin with these two references. Applicants note that in order to establish a prima facie case of obviousness, in addition to other requirements, the prior art references must teach or suggest all the claim limitations. In *re* Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In response to this argument, as applicants noticed that Geistlich and Murdock are only cited for teaching cross-linked polyacrylamide and closed cell foam for delivering active agents to a wound. Using carbonate salts as catalyst for peroxide is taught by Aubry and Hoshino. Formation of oxygen within a polymer matrix is taught by Ladin, and Ladin further suggested polyacrylamide. The present invention as a whole is taught by the combination of the cited references. One cannot show nonobviousness by attacking the references individually where the rejections are based on combination of

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references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986).

It is further noted that the present claims are directed to a product by a process, and not process of making. Product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir.1985). The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). Since the present wound dressing is substantially identical to the dressing taught by the combination of the cited references, the burden is on applicants to show an unobvious difference. "The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974); *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289,

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292 (Fed. Cir.1983). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

The examiner believes that the prima facie case of obviousness has been established because:

(i) There is motivation to combine the references, and motivation is in the references themselves, as set forth in this office action. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985)

(ii) Reasonable expectation to achieve the present invention exists. Combination of references will provide cross-linked polyacrylamide closed cell foam matrix containing oxygen that is produced by the reaction of peroxide and carbonate catalyst, as applicants have done. It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

(iii) The combination of the cited prior art teaches the present invention as a whole. In the light of the foregoing discussion, the Examiner's ultimate legal conclusion

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is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Applicants argue that for at least the reasons indicated above, the pending dependent claims patentably define over the references cited. It is believed that some or all of these claims may possess features that are independently patentable, regardless of the patentability of the independent claims 1, 38, and 39.

In response to this argument, it is argued that the dependent claims are unpatentable for the above reasons and are obvious over the prior art of record.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571)272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on (571) 272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis Ghali/  
Primary Examiner, Art Unit 1611

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